Nos. 14-1418, -1453, -1505, 15-35, -105, -119, & -191

In the Supreme Court of the United States

DAVID A. ZUBIK, *et al.*,

Petitioners,

v.

SYLVIA BURWELL, *et al.*,

Respondents.

On Writs of Certiorari to the United States Courts of Appeals for the Third, Fifth, Tenth and D.C. Circuits

BRIEF OF THE NATIONAL HEALTH LAW PROGRAM, AMERICAN PUBLIC HEALTH ASSOCIATION, NATIONAL HISPANIC MEDICAL ASSOCIATION, NATIONAL FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOCIATION, NATIONAL WOMEN'S HEALTH NETWORK, IPAS, ASIAN AMERICANS ADVANCING JUSTICE | AAJC, ASIAN AMERICANS ADVANCING JUSTICE - LOS ANGELES, ASIAN & PACIFIC ISLANDER AMERICAN HEALTH FORUM, BLACK WOMEN'S HEALTH IMPERATIVE, AND CHRISTIE'S PLACE AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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INTEREST OF THE *AMICI*[1]

The *amici curiae* are the National Health Law Program, American Public Health Association, National Hispanic Medical Association, National Family Planning & Reproductive Health Association, National Women's Health Network, Ipas, Asian Americans Advancing Justice | AAJC, Asian Americans Advancing Justice – Los Angeles, Asian & Pacific Islander American Health Forum, Black Women's Health Imperative, and Christie's Place. While each *amicus* has particular interests, they collectively bring to the Court an in-depth understanding of the impact of cost-sharing on health care service utilization, including on contraception, and existing federal laws and programs that address coverage of and access to contraception. The *amici* want to bring accurate information on these topics to the Court as it considers the legality of the requirements for preventive health care services under § 2713(a)(4) of the Public Health Service Act, added by the Patient Protection and Affordable Care Act (ACA).

SUMMARY OF ARGUMENT

The ACA seeks to address the lack of adequate and affordable health insurance coverage—and, thus, inadequate access to health care. In line with this goal, the ACA recognizes that preventive health services are

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[1] Counsel for the parties have filed with the Clerk blanket consent to *amicus* briefs in this case. No party's counsel authored this brief in whole or in part. No party or party's counsel contributed money to fund preparation or submission of this brief. No person, other than *amici* and *amici*'s counsel, contributed money intended to fund preparation or submission of this brief.

critical to individual and community health and that cost is a barrier to access. The ACA seeks to build upon existing federal laws and increase access to preventive health care services by requiring most group health plans and health insurance issuers to cover, without cost-sharing, women's preventive health care services identified in guidelines issued by the United States Department of Health and Human Services, Health Resources and Services Administration.[2] These laws and policies ensure that all women, regardless of where they work, have seamless access to all Food and Drug Administration (FDA)-approved methods of contraception without cost-sharing. Implementing regulations also include a provision to accommodate the sincerely held religious beliefs of certain non-profit employers with religious objections to contraception.[3]

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[2] *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 2713(a)(4), 124 Stat. 119, 131 (codified at 42 U.S.C. § 300gg-13(a)(4)); U.S. Dep't of Health & Human Servs. (HHS), Health Res. & Servs. Admin., *Women's Preventive Services: Required Health Plan Coverage Guidelines*, http://www.hrsa.gov/womensguidelines (last visited Feb. 10, 2016).

[3] 45 C.F.R. § 147.131(b) (defining "eligible organization").

ARGUMENT

I. The cost of health care impedes access to health care.

One of the basic functions of government is to ensure the health and well-being of its population. Americans have not been receiving recommended health care services, however.[4] Prior to 2010, individuals used preventive services at about half the recommended rate.[5] Low-income individuals and people of color used fewer preventive care services than non-Hispanic whites.[6] Research showed that individuals did not access medically necessary health care services, in part, due to cost.[7] Compared to men, women were

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[4] *See, e.g.*, Elizabeth A. McGlynn et al., *The Quality of Health Care Delivered to Adults in the United States*, 348 NEW ENG. J. MED. 2635, 2636, 2643 (2003) (discussing a 2003 study of adults living in 12 metropolitan areas in United States).

[5] P'ship for Prevention., Preventive Care: A National Profile on Use, Disparities, and Health Benefits 8 (2007), http://www.rwjf.org/content/dam/farm/reports/reports/2007/rwjf13325 ("Among the 12 preventive services examined in this report, 7 are being used by about half or less of the people who should be using them. Racial and ethnic minorities are getting even less preventive care than the general U.S. population."); *see also* McGlynn et al., *supra* note 4, at 2641 (finding "46.5% of participants did not use recommended care").

[6] Lawrence O. Gostin, *Securing Health or Just Health Care? The Effect of the Health Care System on the Health of America*, 39 ST. LOUIS U. L. J. 7, 32 (1994); P'ship for Prevention, supra note 5, at 7.

[7] *See* Geraldine Oliva et al., *What High Risk Women are Telling Us about Access to Primary and Reproductive Health Care and HIV*

"more likely to forgo needed care because of cost and to have problems paying their medical bills, accrue medical debt, or both."[8] The "[d]ifferences between men and women who reported problems accessing needed care persisted across all income groups, but were widest among adults with moderate incomes," according to a 2009 study.[9] That study found that sixty-five percent of women with incomes between $20,000 and $39,999 experienced problems accessing health care services because of cost.[10]

II. Health insurance helps remove cost barriers to health care access.

By expanding the availability of affordable and quality health insurance through the ACA, Congress sought to meet the health care needs of the nation. Health insurance, Congress recognized, is an effective tool for helping people afford the health care they need. An extensive body of research clearly establishes that the lack of adequate health insurance negatively

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Prevention Services, 11 AIDS PREVENTION PREVIEW 513, 516-17, 522 (1999); Amal N. Trivedi et al., *Effect of Cost-sharing on Screening Mammography in Medicare Health Plans*, 358 NEW ENG. J. MED. 375, 381-82 (2008).

[8] Sheila D. Rustgi et al., The Commonwealth Fund, *Women at Risk: Why Many Women Are Forgoing Needed Health Care* 1-2 (2009), http://www.commonwealthfund.org/~/media/Files/Publications/Issue%20Brief/2009/May/Women%20at%20Risk/PDF_1262_Rustgi_women_at_risk_issue_brief_Final.pdf.

[9] *Id.* at 4.

[10] *Id.*

impacts access to health care and health status.[11] Health insurance offers two primary values.[12] One is financial protection: health insurance pays for the cost of medical care so that a person does not have to pay out-of-pocket at the point of service.[13] The second is health protection: "[h]ealth insurance provides access to health care, usefully increasing the care one receives."[14]

The ACA reflects a "comprehensive national plan" to "increase the number of Americans covered by health insurance . . . ."[15] Congress implemented this plan within the existing health care financing system in which employer-sponsored health insurance

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[11] *See, e.g.*, Jack Hadley, *Insurance Coverage, Medical Care Use, and Short-term Health Changes Following an Unintentional Injury or the Onset of a Chronic Condition*, 297 J. OF AM. MED. ASS'N 1073 (2007) (finding that uninsured people are less likely to receive medical care and more likely to have poor health status); Inst. of Med. of the Nat'l Acads. (IOM), *Care Without Coverage: Too Little, Too Late* (2002) (concluding that Americans without health insurance are less likely to receive medical care and more likely to receive care too late, to be sicker, and die sooner).

[12] Dahlia K. Remler & Jessica Greene, *Cost-Sharing: A Blunt Instrument*, 30 ANNUAL REV. PUB. HEALTH 293, 295 (2009); *see also* Allison K. Hoffman, *Three Models of Health Insurance: The Conceptual Pluralism of the Patient Protection and Affordable Care Act*, 159 U. PA. L. REV. 1873, 1876-79 (2011).

[13] Remler & Greene, *supra* note 12, at 295.

[14] *Id.*

[15] *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 132 S. Ct. 2566, 2580, 2606 (2012).

coverage plays an outsized role, and federal funding is limited. In 2009, for example, sixty-one percent of nonelderly individuals obtained health insurance through an employer.[16] Meanwhile, twenty percent of nonelderly individuals were covered by Medicaid, the Children's Health Insurance Program (CHIP), and Medicare.[17] Another seventeen percent—or forty-five million—nonelderly individuals were uninsured.[18]

Under the ACA, the large majority of previously uninsured Americans are intended to gain coverage through federally subsidized options.[19] Specifically, Congress expanded Medicaid to cover millions of low-income nonelderly adults.[20] Congress made federal subsidies available to individuals without employer-sponsored coverage or other affordable health coverage options.[21] Congress also created small business tax credits and the Small Business Health Options

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[16] Cong. Budget Off., *Key Issues in Analyzing Major Health Insurance Proposals* 4 (2008), https://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/99xx/doc9924/12-18-keyissues.pdf.

[17] *Id.*

[18] *Id.*

[19] Matthew Buettgens et al., Urban Inst. & Robert Wood Johnson Found., *America Under the Affordable Care Act* 1, 1, 4 (2010).

[20] 42 U.S.C. § 1396d(y).

[21] 26 U.S.C. § 36B (premium tax credits); 42 U.S.C. § 18071 (cost-sharing reductions).

Program to reduce the cost of providing health insurance coverage for small employers.[22]

At the same time, Congress recognized that 160 million individuals were already covered through employer-sponsored private health insurance.[23] For these individuals, Congress put in place mechanisms to ensure that after the ACA went into effect, employers would continue covering these individuals.[24] For this reason, the ACA imposes a shared-responsibility requirement on large employers to encourage them to offer health insurance to their employees and discourage them from shifting the cost of caring for their employees onto the government.[25] Congress simultaneously adopted provisions that would not only improve the quality of that existing employer-sponsored coverage but would also make it easier for employees to use their insurance to access covered health care services.[26]

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[22] 42 U.S.C. § 18031(b)(1)(B) (Small Business Health Options Program); 26 U.S.C. § 45R (small employer health insurance credit).

[23] Cong. Budget Off., *supra* note 16, at 4.

[24] *See* 26 U.S.C. §§ 4980H(a) (penalizing large employers who do not offer affordable minimum coverage to employees); 36B(c)(2)(C)(i)(II) (employer-sponsored coverage is unaffordable if the employee's share of the premium for self-only care is more than 9.5% of household income); 4980H(b)-(d) (employer penalized if employer failed to offer insurance meeting affordability and adequacy standards).

[25] *Id.* § 4980H(a), (b)-(d).

[26] *See* discussion *infra* Part VI.

III. Cost-sharing prevents individuals from using health care services.

Individuals pay for their health insurance through premiums and cost-sharing.[27] Cost-sharing is the portion of health care expenses not covered by the insurer that the insured must pay out-of-pocket.[28] Cost-sharing includes deductibles, which are the amounts a person must pay out-of-pocket before the insurer will cover any expenses during a given benefit period, as well as copayments and coinsurance that insureds must pay out-of-pocket when they use a service or purchase a product (*e.g.*, for a doctor visit or prescription drug).[29] The imposition of cost-sharing at the point of service is generally justified as a means of discouraging the use of non-essential services and reducing costs, though its efficacy at achieving these goals is not established.[30]

What is clear is that cost-sharing is a barrier to accessing preventive care.[31] A large body of literature

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[27] David Machledt & Jane Perkins, *Medicaid Premiums & Cost-Sharing* 1 (2014), http://www.healthlaw.org/about/staff/david-machledt/all-publications/Medicaid-Premiums-Cost-Sharing#.

[28] Remler & Greene, *supra* note 12, at 294.

[29] *Id.*

[30] Emmett B. Keeler, Rand Corp., *Effects of Cost Sharing on Use of Medical Services and Health*, 8 MED. PRAC. MGMT 317, 318-19 (1992), http://www.rand.org/pubs/reprints/RP1114.html.

[31] *See, e.g.*, Geetesh Solanki et al., *The Direct and Indirect Effects of Cost-Sharing on the Use of Preventive Services*, 34 HEALTH SERVS. RESEARCH 1331, 1347-48 (2000); Remler & Greene, *supra*

concludes that cost-sharing reduces use of medically necessary, valuable services, as opposed to merely discouraging overuse of unnecessary services.[32]

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note 12, at 296 ("Even modest cost-sharing may dissuade people from preventive care that might provide great value in the future."); Andrew J. Karter, et al., *Out-of-Pocket Costs and Diabetes Preventive Services: The Translating Research Into Action for Diabetes (TRIAD) study*, 26 DIABETES CARE 2294, 2296 (2003) (recommending plans and employers evaluate impact of cost-sharing on use of preventive care); Kathleen N. Lohr et al., RAND Corp., *Use of Medical Care in the RAND Health Insurance Experiment: Diagnosis- and Service-Specific Analyses in a Randomized Controlled Trial* 30 (1986), http://www.rand.org/content/dam/rand/pubs/reports/2006/R3469.pdf (finding that cost-sharing is more likely to reduce visits for preventive care than chronic care).

[32] *See generally* Katherine Swartz, Robert Wood Johnson Found., *Cost-Sharing: Effects on Spending and Outcomes* (2010), http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2010/rwjf402103/subassets/rwjf402103_1; Solanki et al., *supra* note 31, at 1347-48; Robert H. Brook et al., RAND Corp., *The Health Insurance Experiment: A Classic RAND Study Speaks to the Current Health Care Reform Debate* 3 (2006), http://www.rand.org/pubs/research_briefs/RB9174.html. For example, studies have shown increased adherence to key preventive medications, such as hypertensives, when cost-sharing was reduced or eliminated. *See* Niteesh K. Choudhry et al., *Full Coverage for Preventive Medications after Myocardial Infarction*, 365 NEW ENG. J. MED. 2088, 2091-96 (2011); Niteesh K. Choudhry et al., *At Pitney Bowes, Value-Based Insurance Design Cut Copayments and Increased Drug Adherence*, 29 HEALTH AFF. 1995, 1995 (2010). Such medications are among the most cost effective treatments available, and better adherence has been consistently associated with improved health outcomes. Michael T. Eaddy et al., *How Patient Cost-Sharing Trends Affect Adherence and Outcomes: A Literature Review*, 37 PHARMACY & THERAPEUTICS 45, 47 (2012).

According to the Institute of Medicine (IOM), a division of the National Academies of Sciences, Engineering, and Medicine, "[s]tudies have . . . shown that even moderate copayments for preventive services . . . deter patients from receiving those services."[33] The RAND Health Insurance Experiment (HIE), conducted from 1971 to 1986, remains the longest-term randomized experiment studying the impact of cost-sharing on medical service utilization and health outcomes.[34] The HIE found that although higher cost-sharing reduced overall use of services and total health care expenditures, it also reduced use of essential health care services and produced some negative health outcomes.[35] The reductions in utilization found by the HIE were more prevalent in the context of preventive care than chronic care and particularly prevalent in the rate of care sought by low-income people.[36]

A 2001 to 2004 study of 366,745 patients enrolled in 174 Medicare managed care plans found that the imposition of cost-sharing reduced mammography screening.[37] The study concluded that "[f]or cost-effective preventive services such as mammography, exempting elderly beneficiaries from cost-sharing may

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[33] IOM, *Clinical Preventive Services for Women: Closing the Gaps* 19 (2011).

[34] Keeler, *supra* note 30, at 320.

[35] *Id.* at 318-19; Brook et al., *supra* note 32, at 2.

[36] Kathleen N. Lohr et al., *supra* note 31, at 29.

[37] Trivedi et al., *supra* note 7, at 381-82.

increase rates of appropriate use."[38] Another study of 11,000 employees with employer-sponsored coverage found that cost-sharing reduced use of pap smears, preventive counseling, and mammography.[39]

IV. Cost prevents women from accessing contraception, particularly the most effective methods of contraception.

High out-of-pocket costs are one of the major barriers to consistent contraceptive use by women.[40] It is not surprising, then, that lower-income women are the least likely to have the resources to obtain reliable methods of family planning and are the most likely to be impacted negatively by unintended pregnancy.[41]

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[38] *Id.*

[39] Solanki et al., *supra* note 31, 1342-43; *see also* Machledt & Perkins, *supra* note 27, at 2-3.

[40] Su-Ying Liang et al., *Women's Out-of-Pocket Expenditures and Dispensing Patterns for Oral Contraceptive Pills between 1996 and 2006*, 83 CONTRACEPTION 491, 531 (2010); *see also* IOM, *Clinical Preventive Services for Women: Closing the Gaps*, *supra* note 33, at 109.

[41] *See* Rustgi et al., *supra* note 8, at 4-5 (explaining that women's lower incomes and higher demands for health care, as compared to men, put them at increased risk for accruing medical debt and likelihood of putting off care); Lawrence B. Finer & Stanley K. Henshaw, *Disparities in Rates of Unintended Pregnancy in the United States, 1994 and 2001*, 38 PERSP ON SEXUAL & REPROD. HEALTH 90, 92-94 (2006) (finding that women with lower incomes have higher rates of unintended pregnancy as compared to women with higher incomes).

A 2010 study found that privately insured women with prescription drug coverage paid, out-of-pocket, on average, $14 per oral contraceptive pill pack or approximately half of the cost of the pills.[42] Studies consistently find that "[e]ven small increments in cost sharing have been shown to reduce the use of preventive services."[43] The IOM has accordingly recognized that the "elimination of cost-sharing for contraception therefore could greatly increase its use, including use of the more effective and longer-acting methods."[44]

In this regard, the California Kaiser Foundation Health Plan's experience is informative. The California Kaiser Foundation Health Plan eliminated copayments for the most effective contraceptive methods in 2002.[45] Prior to the change, users paid up to $300 for a five-year contraceptive method; after elimination of the copayment, use of these methods increased by 137%.[46]

Similarly, the Contraceptive CHOICE Project—a large prospective cohort study of nearly 10,000 adolescents and women in the St. Louis, Missouri area—provided participants a choice of no-cost

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[42] Liang et al., *supra* note 40, at 530-31.

[43] IOM, *Clinical Preventive Services for Women: Closing the Gaps*, *supra* note 33, at 109.

[44] *Id.*

[45] Kelly Cleland et al., *Family Planning as Cost-Saving Preventive Health Service*, 364 NEW ENG. J. MED. e.37(1), e.37(2) (2011).

[46] *Id.*

contraception and followed them for two to three years.[47] The study concluded that providing no-cost contraception significantly allowed young women to avoid unintended pregnancy resulting in reduced abortion and teenage birth rates.[48] Specifically, between 2008 and 2010, the abortion rate of study participants ranged from 4.4 to 7.5 per 1,000 teens compared to the national average of 19.6 per 1,000 teens.[49] The study participant teen birth rate was 6.3 per 1,000 teens compared to the national average of 34.1 per 1,000 teens.[50] The researchers concluded that providing access to no-cost contraception greatly increased the ability of adolescents and women in the St. Louis region to select the most effective methods of contraception, thereby allowing them to reduce unintended pregnancies and abortions.[51] Based on their findings, the researchers estimated that providing no-cost contraception to all women would allow them to avoid unintended pregnancy and prevent as many as

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[47] Jeffrey F Peipert et al., *Preventing Unintended Pregnancies by Providing No-Cost Contraception*, 120(6) OBSTETRICS & GYNECOLOGY 1291, 1291-92 (2012).

[48] *Id.* at 1295-96.

[49] *Id.* at 1294.

[50] *Id.* The researchers "evaluated teenage birth as a proxy for unintended pregnancy, as up to 80% of these births are unintended." *Id.*

[51] *Id.* at 1295-96.

forty-one to seventy-one percent of abortions in the United States annually.[52]

V. By eliminating cost barriers, the ACA helps ensure access to contraception.

The ACA reflects the well-documented body of research that out-of-pocket costs for health care services are a problematic barrier to medication adherence. [53] By removing cost barriers, the ACA and its implementing regulations seek to increase access to contraception. And, the ACA is proving to be effective at achieving this compelling governmental interest. In the Guttmacher Institute's Continuity and Change in Contraceptive Use study, researchers surveyed women aged eighteen to thirty-nine years about their contraceptive use before and after the contraceptive coverage requirement went into wide-scale effect.[54] The

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[52] *Id.* at 1291-97

[53] *See, e.g.*, Michael E. Chernew et al., *Impact of Decreasing Copayments on Medication Adherence Within a Disease Management Environment*, 27 HEALTH AFF. 103, 111 (2008) (finding that "increased cost sharing leads to decreased adherence to potentially life-saving medications, with likely serious deleterious health effects"); Niteesh K. Choudhry et al., *Should Patients Receive Secondary Prevention Medications for Free After a Myocardial Infarction? An Economic Analysis*, 26 HEALTH AFF. 186, 186 (2007) (finding that cost-sharing can cause medication underuse).

[54] Adam Sonfield et al., *Impact of the federal contraceptive coverage guarantee on out-of-pocket payments for contraceptives: 2014 update*, 91 CONTRACEPTION 44, 44-45 (2014). The federal government phased in the contraceptive coverage requirement starting in August 2012, and it went into wide-scale effect in January 2013. *Id.* at 44.

results show that the proportion of privately insured women with no out-of-pocket cost for their oral contraceptives increased from fifteen percent to sixty-seven percent; for injectable contraception, from twenty-seven percent to fifty-nine percent; for the vaginal ring, from twenty percent to seventy-four percent; and for the intrauterine device, from forty-five percent to sixty-two percent.[55] As rates of contraceptive coverage without cost-sharing increased, so did contraceptive use.[56] A report from the IMS Institute for Healthcare Informatics found that 24.4 million more prescriptions for oral contraceptives with no copayment were filled in 2013 than in 2012.[57] According to that report, oral contraceptives accounted for the largest increases in prescriptions dispensed without a copayment.[58] Reducing the cost barrier to contraception is resulting in greater access to contraception, just as the ACA intended.

VI. Nonfinancial barriers prevent or delay individuals from receiving the health care they need.

The existence of affordable health care coverage of contraception is not enough, however, to ensure appropriate access to contraception; instead, women

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[55] *Id.* at 45-47.

[56] *See* IMS Inst. for Healthcare Informatics, *Medicine Use and Shifting Costs of Healthcare: A review of the use of medicines in the United States in 2013* (2014).

[57] *Id.* at 16.

[58] *Id.* at 13.

must also be able to actually use that coverage for timely access to their desired contraceptive method. Yet, as the IOM has recognized, "[e]ven highly skilled individuals may find the [health] system[ ] too complicated to understand . . . ."[59] To meet the health care needs of the nation, Congress therefore had to not only expand the availability, affordability, and quality of health insurance, but also address other, nonfinancial barriers that lead to unmet need or delayed care.[60] The ACA and its implementing regulations accordingly attempt to make it easier for individuals to apply for and enroll in a health care program, compare and choose a health plan, understand the scope of covered benefits, find a provider to access those covered benefits, and file a grievance when they believe they have been wrongfully

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[59] IOM, *Health Literacy: A Prescription to End Confusion* 11 (Lynn Nielsen-Bohlman et al. eds., 2004).

[60] *See, e.g.*, Jeffrey T. Kullgren et al., Robert Wood Johnson Found. *Nonfinancial Barriers and Access to Care for U.S. Adults* 462, 465 (2011) (finding that nonfinancial barriers lead to unmet need or delayed care, and that the ACA will not "translate into actual population-level improvements in access without concurrent efforts to reduce nonfinancial barriers").

denied services.[61] Unfortunately, notwithstanding these efforts, barriers to care continue to exist.[62]

Notably, underlying these governmental efforts is the recognition that the more complicated or difficult it is to navigate the path to care, the more likely a person is to forgo or delay receiving care. This notion is supported not only by common sense, but also by research.[63] Petitioners' proposed alternatives, on the other hand, undermine such efforts by creating additional hurdles rather than removing them. And,

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[61] *See, e.g.*, 42 U.S.C. § 18083 (single-streamlined application); *id.* § 300gg-15 (requiring summary of benefits and coverage document to "accurately describe the benefits and coverage under the applicable plan"); 42 U.S.C. § 18031(c)(1) (requiring plans to provide information regarding provider availability); *id.* § 300gg-93 (addressing insurance consumer information, including appeals and grievance processes).

[62] Laurie Sobel et al., Kaiser Family Found., *Coverage of Contraceptive Services: A Review of Health Insurance Plans in Five States* (2015) (finding problems accessing full range of contraception even after ACA's contraceptive coverage provision went into effect).

[63] *See, e.g.*, Diana Greene Foster et al., *Attitudes Toward Unprotected Intercourse and Risk of Pregnancy Among Women Seeking Abortion*, 22 WOMEN'S HEALTH ISSUES e149, e154 (2011) (recommending that contraceptives "be made easy to procure and use"); *see also generally* Mary E. Reed et al., *In Consumer-Directed Health Plans, A Majority Of Patients Were Unaware Of Free Or Low-Cost Preventive Care* 31 HEALTH AFF. 2641, 2648 (2012) (finding that confusion around health plan details created barriers to care); Sheila Hoag et al., Mathematica Pol'y Res. & Urban Inst., *CHIPRA Mandated Evaluation of Express Lane Eligibility: First Year Findings* xi (2012), https://aspe.hhs.gov/sites/default/files/pdf/76596/rpt.pdf.

Petitioners would be ineffective at achieving the government's compelling interests. In the first instance, it is unclear how the government is expected to identify employees and dependents enrolled in Petitioners' health plans since Petitioners object to providing identifying information to the government. Moreover, each of Petitioners' alternatives would require employees and their dependents to take additional steps to obtain contraceptives elsewhere, as explained in more detail in other briefs filed with the Court (*e.g.*, identify and enroll in another health plan or health insurance program, receive contraceptive care from one provider and other primary and preventive care from another provider, pay up-front costs and seek reimbursement later). Petitioners dismiss the impact that these burdens would have on women. However, studies assessing the attitudes and behaviors associated with unintended pregnancy have found that women engaging in unprotected sex frequently report barriers—financial *and* nonfinancial—in accessing birth control.[64] Nonfinancial barriers include "logistical barriers for access to care, negative healthcare experiences at previous encounters, or language barriers resulting in poor patient-provider

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[64] *See, e.g.*, Oliva et al., *supra* note 7, at 515-21 (identifying barriers to care as including cost of health care, perceived poor quality of care and experiences of discrimination and stigmatization, geographic accessibility, fear of legal/social services punitive actions, misperceptions about the efficacy of birth control methods and condom usage); Adejoke Ayoola et al., *Reasons for unprotected intercourse in adult women*, 41 J. OF WOMEN'S HEALTH 271, 304-09 (2007) (discussing multiple reasons women have unprotected sex).

communication."[65] These, and other, nonfinancial barriers have very real consequences on health outcomes, including deterring or preventing timely access to care.[66] For this reason, research recommends that policies not only make contraceptive methods affordable, but also "simple to . . . obtain."[67] The contraceptive coverage requirement is in accord with this research.

And, the contraceptive coverage requirement seeks to achieve a governmental interest of the highest order. A significant proportion of women (and men) who do not want a pregnancy engage in unprotected sex and thereby risk unintended pregnancy.[68] Indeed, over half of the unintended pregnancies in the United States are experienced by women who did not use contraception

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[65] Loreley Robie et al., *The Use of Patient Navigators to Improve Cancer Care for Hispanic Patients*, 5 CLINICAL MED. INSIGHTS: ONCOLOGY 1, 2 (2011) (concluding patient navigators are an important tool to improving access to care for Hispanic patients).

[66] *See, e.g.*, Kullgren et al., *supra* note 60, at 476 (2011) (finding that nonfinancial barriers lead to unmet need or delayed care, and that the ACA will not "translate into actual population-level improvements in access without concurrent efforts to reduce nonfinancial barriers").

[67] Diana Greene Foster et al., *Attitudes Toward Unprotected Intercourse and Risk of Pregnancy Among Women Seeking Abortion*, *supra* note 63, at e154.

[68] Diana Greene Foster et al., *Willingness to Have Unprotected Sex*, J. OF SEX RES. 1, 7 (2011); M. Antonia Briggs et al., *Unprotected Intercourse among Women Wanting to Avoid Pregnancy: Attitudes, Behavior, and Beliefs*, 22 WOMEN'S HEALTH ISSUES e311, e315-e316 (2012).

during the month of conception.[69] The contraceptive coverage requirement seeks to make contraception affordable and easy to access to enable women to decide when and whether to become pregnant.

VII. The ACA's contraceptive coverage provision is one of many government strategies working together to ensure that all Americans have coverage of and access to necessary health care services.

The ACA's coverage provisions are a part of a long history of federal legislation, dating back to the 1970s, expanding coverage of, and thereby access to, health care services, including contraceptive counseling, services, and supplies. These prior expansions, however, were not designed to achieve the ACA's goal of fully ensuring access to this critical preventive service. Moreover, while these laws are interconnected, none of them could simply be expanded to absorb the coverage and cost of the otherwise privately insured women at issue here. Rather, with limited scope and funding, all of these provisions must work together for the government to achieve its goal of ensuring coverage of and access to contraception.

For example, when the federal government functions as an employer, it provides health insurance coverage to its employees. And, that coverage includes contraception. Federal legislation regulating health services available to military personnel and their families requires coverage of preventive contraceptive services. Pursuant to congressionally delegated

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[69] Finer & Henshaw, *supra* note 41, at 92.

authority, the Department of Defense established the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) in 1967.[70] In 1995, the Department of Defense established TRICARE as a "comprehensive managed health care program for the delivery and financing of health care services in the Military Health System."[71] TRICARE provides health care benefits to approximately 8.9 million active-duty service members, retirees, and their families, and other beneficiaries from any of the seven services in the United States.[72] TRICARE offers all beneficiaries FDA-approved methods of contraception, including intrauterine devices, diaphragms, prescription contraceptives, and surgical sterilization.[73]

The Federal Employees Health Benefits (FEHB) program provides employee health benefits to civilian government employees and annuitants of the United States government.[74] The United States Office of Personnel Management contracts with qualified

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[70] Pub. L. No. 85-861, § 1(25)(B), 72 Stat. 1450 (1958), amended by Pub. L. No. 89-614, § 2(1), 80 Stat. 862 (1966) (codified at 10 U.S.C. §§ 1071-1110b).

[71] 32 C.F.R. § 199.17(a).

[72] *See* 10 U.S.C. §§ 1071-1110b; TRICARE, *Beneficiaries by Location* (2016), http://www.tricare.mil/About/Facts/BeneNumbers/States.aspx.

[73] 10 U.S.C. § 1074d(b)(3) (preventive health care services for women includes pregnancy prevention); 32 C.F.R. § 199.4(e)(3) (scope of family planning benefit).

[74] *See* 5 U.S.C. §§ 8901-8914 (health insurance for government employees), 8905(a)-(b) (defining eligible persons).

private insurance carriers to offer health care plans through the FEHB program.[75] As part of the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999, Congress approved a "contraceptive equity provision" requiring most FEHB plans to cover contraception.[76] Today, the United States Office of Personnel Management requires FEHB plans to cover the full range of FDA-approved contraceptive drugs and devices without cost-sharing.[77] As amended, the FEHB program provides that specifically enumerated religious health plans do not have to cover contraception and allows for the potential that future plans objecting to contraceptive coverage "on the basis of religious beliefs" will be included."[78] However, unlike here where Petitioners seek to prescribe the choices of their employees, the employees enrolled in FEHB plans

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[75] *Id.* § 8902; *Muratore v. U.S. Off. of Pers. Mgmt.*, 222 F.3d 918, 920 (11th Cir. 2000) ("Congress enacted the FEHBA . . . to create a comprehensive program of subsidized health care benefits for federal employees and retirees."); U.S. Off. of Pers. Mgmt. (OPM), *The Fact Book, Federal Civilian Workforce Statistics* 82 (2007), http://www.opm.gov/feddata/factbook/.

[76] Omnibus Consolidated & Emergency Supplemental Appropriations Act of 1999, Pub. L. No. 105-277, § 656(a), 112 Stat. 2681 (1998).

[77] OPM, *Federal Employees Health Benefits (FEHB) Program: Expanded Coverage of Contraceptives for 1999*, Ltr. No. 98-418 (Nov. 6, 1998); OPM, *Federal Employees Health Benefits Program Call Letter*, Ltr. No. 2012-09 at 2 (Mar. 29, 2012).

[78] Pub. L. No. 105-277, § 656(b), 112 Stat. 2681, *supra* note 76; *see also* Cong. Res. Servs., *Laws Affecting the Federal Employees Benefits Program (FEHBP)* (2013), https://www.fas.org/sgp/crs/misc/R42741.pdf.

make the decision of whether to have contraceptive coverage.

The federal government also uses public programs to help provide health care access when individuals lack other affordable options. But, these public programs were not created to pay for the cost of caring for Petitioners' employees—higher income, privately insured, employed individuals. Medicaid, for instance, requires participating states to cover family planning services and supplies without cost-sharing.[79] Medicaid is the country's largest public health insurance program.[80] It is designed, not as a source of coverage for the entire nonelderly population, but for low-income individuals who lack the financial means to pay for their health care.[81] States choose to participate in the Medicaid program; if they decide to participate, they receive significant federal funding in return for providing health coverage to specified low-income persons.[82] Since its adoption in 1965, Congress has

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[79] 42 U.S.C. § 1396d(a)(4)(C) (requiring family planning services and supplies to be covered in Medicaid programs); *id.* U.S.C. § 1396u-7(b)(7) (added by ACA § 2303(C) and referring to § 1396d(a)(4)(C)) (extending family planning services and supplies requirement to Medicaid benchmark plans).

[80] *See* Julia Paradise, Kaiser Fam. Found., *Medicaid Moving Forward* 1 (2015) (finding Medicaid covers approximately seventy million people).

[81] 42 U.S.C. § 1396a(a)(10)(A)(i)(VIII).

[82] *See* 42 U.S.C. § 1396d(b); *Wilder v. Va. Hosp. Ass'n*, 496 U.S. 498, 502 (1990) ("Although participation in the program is voluntary, participating states must comply with certain requirements imposed by the Medicaid Act and regulations.").

expanded Medicaid significantly.[83] Most recently, Congress expanded Medicaid through an ACA provision that extends coverage to lower-income, non-disabled, non-elderly adults—an expansion that *National Federation of Independent Business v. Sebelius* effectively made optional for the states.[84] And, although the federal government can encourage states to expand their family planning-only programs, through an ACA-created state plan amendment option, states decide whether to do so.[85] Yet, despite the role it plays, the health care needs of the population already exceed the capabilities of Medicaid.[86]

Government programs also support health care access and services for an estimated 3.7 million American Indians and Alaska Natives.[87] American Indians and Alaska Natives are eligible to participate in all public, private, and state health insurance

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[83] Br. for *Amici Curiae* Nat'l Health Law Program et al. at 4-23, *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 132 S.Ct. 2566 (2012) (Nos. 11-393, 11-398, 11-400).

[84] 132 S. Ct. 2566, 2607 (2012) (holding Secretary of HHS cannot deny all federal Medicaid funding to states that do not implement the ACA Medicaid expansion).

[85] *See* 42 U.S.C. § 1396a(a)(10)(A)(ii)(XXI) (family planning state plan amendment option).

[86] *See, e.g.*, Julia Paradise, *supra* note 80, at 7 (discussing challenges and gaps to care).

[87] HHS, Indian Health Serv. (IHS), *Indian Health Disparities* (2015), https://www.ihs.gov/newsroom/includes/themes/newihstheme/display_objects/documents/factsheets/Disparities.pdf.

programs available to the general population.[88] But, on their own, those programs are insufficient to meet the needs of the American Indian and Alaska Native population. The Indian Health Service (IHS), an agency within HHS, exists to provide health care services to approximately 2.2 million American Indians and Alaska Natives.[89] Congress authorized IHS to "provide health promotion and disease prevention services to Indians . . . ."[90] Congress' definition of "health promotion" includes programs for "reproductive health and family planning."[91] IHS "provide[s] comprehensive family planning services to all eligible American Indian and Alaska Native men and women."[92] This includes, "[a]ll available Food and Drug Administration (FDA) approved types of contraceptive (mechanical, chemical and natural) methods," with the individual deciding the appropriate choice of method.[93]

The ACA's health insurance exchanges/ marketplaces were intended to provide insurance

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[88] HHS, IHS, *Basis for Health Services* (2015), https://www.ihs.gov/newsroom/includes/themes/newihstheme/display_objects/documents/factsheets/BasisforHealthServices.pdf.

[89] HHS, IHS, *Indian Health Disparities*, *supra* note 87, at 1.

[90] 25 U.S.C. § 1621b(a).

[91] *Id.* § 1603(11)(G)(xix).

[92] HHS, IHS, *Indian Health Manual* § 3-13.12B(1), https://www.ihs.gov/ihm/index.cfm?module=dsp_ihm_pc_p3c13#3-13.12.

[93] *Id.* §§ 3-13.12F(2), 3-13.12B(1); *see also* 42 U.S.C. §§ 18071(d)(1)-(2).

coverage to individuals who could not afford adequate insurance policies on the private market—not to pay for the care of Petitioners' employees who are otherwise entitled to comprehensive and affordable employer-sponsored coverage. The ACA makes health insurance more affordable through two types of financial assistance available to qualified individuals purchasing insurance through the health insurance exchanges: tax credits to reduce premiums for people with incomes between 100 and 400% federal poverty level (FPL) and cost-sharing reductions to lower out-of-pocket expenses for people with incomes below 250% FPL.[94] Congress designed these federal subsidies to make insurance available to low- to moderate-income individuals who otherwise lacked affordable coverage options. Congress intended the exchanges to cover individuals without access to employer-sponsored insurance, not to be a substitute for employer sponsored-coverage. And, the contraceptive coverage provision at issue here was included to ensure that the coverage employers provide will meet the needs of women.

VIII. Title X is not a substitute for the private health insurance market.

Petitioners' attempts to force Title X to prioritize paying for the health care services of their employees—higher income, privately insured individuals—disregard the purpose and design of that safety net program. In 1970, Congress amended the

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[94] 26 U.S.C. § 36B(b)(3)(A) (premium subsidies); 42 U.S.C. § 18071(c)(2) (cost-sharing reductions).

Public Health Service Act of 1944 by adding Title X.[95] Title X's purpose is to make family planning services and information widely available so that individuals can prevent unintended or unwanted pregnancies.[96] Title X is the nation's only dedicated source of federal funding for safety net family planning services.

For more than forty years, Title X funding has provided for a wraparound and infrastructure program to help ensure that low-income and vulnerable populations "who want . . . but cannot afford" family planning services are able to access them.[97] Federal law accordingly requires Title X providers to give priority to "persons from low-income families."[98] These are families whose total annual income does not exceed 100% FPL or $24,300 for a family of four in the forty-

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[95] *See* Fam. Plan. Servs. & Population Res. Act of 1970, Pub. L. No. 91-572, 84 Stat. 1504.

[96] *See Pl. Parenthood of Am., Inc. v. Schweiker*, 559 F Supp. 658, 660 (D.D.C. 1983) ("Title X was enacted in response to a growing congressional concern with the number of unwanted pregnancies in the United States, and the social and medical costs associated with such pregnancies.").

[97] *See* 42 U.S.C. §§ 300-300a-8; U.S. Off. of Population Aff. (OPA), *Title X Funding History* (last visited Feb. 14, 2016), http://www.hhs.gov/opa/title-x-family-planning/title-x-policies/title-x-funding-history/; President Richard Nixon, Statement on Signing the Family Planning Services and Population Research Act of 1970 (Dec. 26, 1970).

[98] 42 C.F.R. §§ 59.5(a)(6)-(9).

eight contiguous states in 2016.[99] While Title X-funded health centers can provide care to patients whose annual family income exceeds this FPL amount, Title X was never designed (nor funded) to absorb the unmet needs of individuals with private health insurance coverage. Indeed, in 2014, sixty-nine percent of Title X clients had incomes at or below the federal poverty level, ninety-one percent of Title X clients had incomes at or below 250% FPL, and fifty-four percent were uninsured.[100] For sixty-one percent of patients, Title X-funded health centers were their "'usual' or only regular source of health care."[101] Title X steps in as the safety net to assist higher-income individuals who are "unable, for good reasons, to pay for family planning services," for example, individuals who need to receive services on a confidential basis.[102] However, Congress did not design Title X as a substitute for private health insurance coverage. Nor did Congress intend the program as an enabler for employers to force the government to subsidize health care services that federal law otherwise requires private health plans to cover. Title X is designed to subsidize a program of care, not pay all of the cost of any service or activity.

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[99] *Id.* § 59.2 (defining "low income family" for purposes of the Public Health Service Act); Annual Update of the HHS Poverty Guidelines, 81 Fed. Reg. 4036, 4036 (Jan. 25, 2016).

[100] Christina Fowler et al., *Title X Family Planning Annual Report: 2014 National Summary* 22, 22-23 (2015), http://www.hhs.gov/opa/pdfs/title-x-fpar-2014-national.pdf.

[101] Angela Napili, Cong. Res. Serv., *Title X (Public Health Service Act) Family Planning Program* 2 (2015).

[102] 42 C.F.R. § 59.2.

The Title X statute and regulations contemplate that Title X and third-party payers will work together to pay for care, directing Title X-funded agencies to seek payment from such third-party payers.[103]

Title X offers services free of charge only to individuals whose incomes are at or below the FPL.[104] Meanwhile, Title X patients with family incomes between 101-250% FPL are charged "in accordance with a schedule of discounts based on [the patient's] ability to pay."[105] Although Title X-funded health centers are allowed to serve clients with incomes above 250% FPL, women above this income threshold are charged "in accordance with a schedule of fees designed to recover the reasonable costs of providing services."[106] Yet, as discussed above, the contraceptive coverage requirement is intended to remove cost-barriers and eliminate cost-sharing for contraception. Requiring otherwise higher-income, privately insured individuals to use Title X health centers would deplete Title X funds intended for lower income people and defeat the compelling government interest of increasing utilization of preventive contraceptive services by eliminating cost-sharing.

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[103] *See, e.g.*, 42 U.S.C. § 300a-4(c)(2) (prohibiting charging persons from a "low-income family" for family planning services "except to the extent that payment will be made by a third party (including a government agency) which is authorized or is under legal obligation to pay such charge"); 42 C.F.R. §§ 59.5(a)(7), (9).

[104] 42 C.F.R. §§ 59.2, 59.5(a)(7).

[105] *Id.* §§ 59.2, 59.5(a)(8).

[106] *Id.* §§ 59.2, 59.5(a)(8).

Today, Title X is underfunded and overburdened.[107] Since the 1980s, Title X funding "has not kept pace with increased costs of contraceptives, supplies, and diagnostics; greater numbers of people seeking services; inflation; increased costs of salaries and benefits; infrastructure expenses; or insurance costs."[108] The number of women in need of publicly funded contraceptive services and supplies grew twenty-three percent—or by nearly 3.7 million women—between 2000 and 2013.[109] Yet, between the 2010 and 2013 fiscal years, Title X funding decreased by approximately thirty-nine million dollars, or 12.3%.[110] This time period also corresponds with the largest decrease in the number of patients served in Title X sites in more than a decade—a loss of more than 667,000 patients.[111]

Congress designed Title X, and other safety net programs, to fill in gaps and provide access to care for underserved individuals without reasonable alternatives for care. Title X cannot substitute for private health insurance coverage.

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[107] *See* IOM, *A Review of the HHS Family Planning Program: Mission,Management, and Measurement of Results* 126 (2009).

[108] *Id.* at 10-11.

[109] Jennifer J. Frost et al., Guttmacher Inst., *Contraceptive Needs and Services, 2013 Update* 7-8 (2015).

[110] *See* OPA, *supra* note 97.

[111] Christina Fowler et al., *Title X Family Planning Annual Report: 2013 National Summary* 8 (2014), http://www.hhs.gov/opa/pdfs/fpar-2013-national-summary.pdf.

CONCLUSION

Section 2713(a)(4) of the Public Health Service Act, and its implementing regulations, make access to contraception possible by ensuring that health plans in the individual and small group market adequately cover contraception without cost-sharing—cost-sharing that would otherwise reduce use of this necessary service. This Court should find for the Government and uphold the contraceptive coverage provision.

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